

July 1, 2003

James A. Barter, Ph.D.
Director, Environmental Health Sciences & Toxicology
PPG Industries, Inc.
One PPG Place
Pittsburgh, PA 15272

Dear Dr. Barter:

The Office of Pollution Prevention and Toxics is providing the following preliminary comments on the robust summaries and test plan for 1,7-bis(1,3-dimethylbutylidene)diethylenetriamine, posted on the ChemRTK HPV Challenge Program Web site on February 28, 2003. I commend PPG Industries, Inc. and Air Products and Chemicals, Inc. for their commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA agrees that the commercial mixture (70% sponsored substance and 30% methyl isobutyl ketone (MIBK)) is an acceptable test substance because of the formation of polymeric by-products if the excess MIBK is driven off and that 1,7-bis(1,3-dimethylbutylidene)diethylenetriamine is rapidly hydrolyzed to diethylenetriamine (DETA) and MIBK.

No data were submitted for aquatic toxicity or for repeated-dose toxicity, genotoxicity, reproductive toxicity or developmental toxicity. The test plan indicates that these endpoints are to be satisfied by available data on the hydrolysis products DETA and MIBK; however, no actual data were reviewed in the test plan or provided as robust summaries. In addition, no rationale was presented to show that data from separate studies of DETA and MIBK would be representative of the toxicity of the DETA/MIBK mixture that would result from hydrolysis of the submitted substance. For health effects, the submitter needs to provide support for using data from DETA and MIBK separately, or provide test data for either the submitted substance or for its hydrolysis products DETA and MIBK tested together in a molar ratio that mimics the ratio present in unhydrolyzed submitted substance. The latter applies to ecological effects. In addition, when data for other substances are used to address SIDS-related endpoints, robust summaries for the key studies need to be provided.

EPA will post this letter on the HPV Challenge Web site within the next few days. We ask that PPG Industries, Inc. and Air Products and Chemicals, Inc. advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsc hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber